TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 6, 2008.

The board will hold a public hearing starting at 2:30 p.m. on October 29, 2008 at the Radisson San Francisco Airport, 5000 Sierra Point Parkway, Brisbane, California, 94005. At the hearing any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The board requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by sections 4005 and 4127 of the Business and Professions, and to implement, interpret, or make specific sections 4005, 4027, 4033, 4036, 4037, 4050, 4051, 4052, 4059, 4076, 4081, 4127, 4127.7, 4170, 4171, and 4332 of the Business and Professions Code, and section 18944(a) of the Health and Safety Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Existing law provides the authority for a pharmacist to compound drug products as well as compound injectable products.

As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. The proposed changes will provide uniformity in compounding for California consumers.

Below is a summary of each proposed change.

1. Repeal 16 CCR 1716.1. The provisions in 1761.1 are now included within other sections of the regulation proposal.

2. Repeal 16 CCR 1716.2. The provisions in 1761.2 are now included within other

sections of the regulation proposal.

3. Adopt 16 CCR 1735. This new section would define the activities that constitute compounding in licensed pharmacies.

4. Adopt 16 CCR 1735.1. This new section would define the following common compounding terms referenced in the regulation proposal: “integrity”, “potency”, “quality”, and “strength”.

5. Adopt 16 CCR 1735.2. This new section would place limitations on the conditions under which compounding can occur as well as allow for anticipatory compounding only under specified conditions. This section contains the provisions previously contained in section 1716.1 and specifies general requirements for compounding, including the requirement to maintain a master formula record, storage requirements, expiration date requirements, and establishes the self-assessment form requirement.

6. Adopt 16 CCR 1735.3. This new section would specify the pharmacy record requirements for each compounded drug, record requirements for the products used in compounding, as well as the duration of time records must be maintained.

7. Adopt 16 CCR 1735.4. This new section would specify the labeling requirements for compounded drugs in addition to the labeling requirements detailed in Business and Professions Code section 4076.

8. Adopt 16 CCR 1735.5. This new section would establish and define the policy and procedure manual that must be maintained by a pharmacy that compounds medications.

9. Adopt 16 CCR 1735.6. This new section would require that the pharmacy maintain written documentation regarding the facilities and equipment used and specify that all equipment used must be done so in accordance with the manufacturer’s specifications. In addition, equipment used must be calibrated.

10. Adopt 16 CCR 1735.7. This new section would require that the pharmacy maintain written documentation to demonstrate relevant pharmacy personnel are trained and possess the necessary skills to perform responsibilities as well as require the pharmacy to develop and maintain an on-going evaluation for relevant personnel.

11. Adopt 16 CCR 1735.8. This new section would require that the pharmacy, as part of its written policies and procedures manual, maintain a quality assurance plan and specify the required elements of the plan.

12. Amend 16 CCR 1751. This section would be amended to require that pharmacies engage in compounding sterile injectable drug products are required to comply with all requirements specified in sections 1735 through 1735.8, as well as all requirements specified in section 1751 through 1751.8.

13. Amend 16 CCR 1751.1. This section is renumbered from section 1751.3 to 1751.1 to conform with the sequence of Article 4.5 (16 CCR 1735 – 1735.8). In addition, referenced sections were updated to also conform with the requirements in Article 4.5.

14. Amend 16 CCR 1751.2. This section would be amended to include the specific references to labeling requirements contained in Business and Professions Code section 4076, as well as to conform with the labeling requirements in 16 CCR 1735.4.

15. Amend 16 CCR 1751.3. This section is renumbered from 1751.02 to 1751.3 and consolidated to reduce confusion. In addition, it would be reorganized to conform with the sequence of similar subject areas in Article 4.5. Subsection (c) was moved and slightly modified from former section 16 CCR 1751.1, to consolidate similar provisions.

16. (A) Amend 16 CCR 1751.4. This section is renumbered from 1751.01 to 1751.4 and consolidated with former sections 1751.1 and 1751.3.

    (B) Section 1751.1 is being repealed. This section is consolidated with the new section 1751.4.

    (C) Section 1751.3 is being repealed. This section is consolidated with the new section 1751.4.

17. Amend 16 CCR 1751.5. This section is renumbered from 1751.4 to 1751.5.

18. Amend 16 CCR 1751.6. This section is renumbered from 1751.5 to 1751.6.

19. Amend 16 CCR 1751.7. This section would be amended to include that any pharmacy engaged in sterile injectable compounding must include a written quality assurance plan as part of its written policies and procedures and that batch-produced sterile to sterile transfers are subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

20. Amend 16 CCR 1751.8. This section is renumbered from 1751.9 to 1751.8 and slightly modified to use consistent language throughout Article 7.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board determined that the proposed regulatory action would have no significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This proposal would apply to all pharmacies. Nonresident pharmacies providing compounded medications to California residents would also need to comply with this regulation, providing parity for business and consumer protection to Californians.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is aware that pharmacies that compound medicine will incur the cost of end-product testing. The estimated costs for such testing are about $100.00 per test. This is a one-time cost as long as the compounding process remains the same.

This board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact on affected pharmacies.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy estimates that approximately 540 pharmacies impacted by this regulation could be small business. The board anticipates that the changes proposed and associated costs will not be of sufficient magnitude to have the effect of creating or eliminating small business.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative which it considered either would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

The proposed text and the document proposed herein are provided in this mailing.

Copies of the exact language of the proposed regulations, the self-assessment form being incorporated by reference in this proposal and the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Karen Cates
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7914
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The backup contact person is:

Name:	Anne Sodergren
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Web site Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.